**IN THE UNITED STATES DISTRICT COURT**
**EASTERN DISTRICT OF OKLAHOMA**

HARVEY BRYANT,

Plaintiff,

v.

UPSHER-SMITH LABORATORIES, INC.

Defendant.

Case No. CIV 10-410-SPS

# COMPLAINT

## I. INTRODUCTION & NATURE OF ACTION

1. Plaintiff, Harvey Bryant, is an individual residing in Tishomingo, Oklahoma. Plaintiff was first prescribed and began using Amiodarone which was manufactured and/or distributed by Upsher-Smith Laboratories, Inc. ("Upsher") as Pacerone. He began taking Pacerone beginning in or about April 2001 and continued such use throughout 2001. As a direct and proximate result of ingesting Pacerone, Mr. Bryant suffered severe eye damage and vision loss. He is confined to his home and Plaintiff has suffered and continues to suffer pain, suffering, and other damages as a result of his injuries.

2. Plaintiff Bryant suffers from blindness and optic neuropathy as the result of consuming a product, Defendant's Pacerone, which was manufactured, supplied, sold, and distributed by Defendant Upsher.

3. Defendant's Amiodarone (hereinafter "Amiodarone" or "Pacerone") is the branded generic equivalent of Cordarone® manufactured and distributed by non-party Wyeth Pharmaceuticals ("Wyeth"). Defendant Upsher markets its Amiodarone product as Pacerone.



consent form provided

4. Plaintiff consumed Defendant's Amiodarone throughout 2001. Prescription records and the NDC No. confirm Plaintiff consumed Defendant's Amiodarone.

5. Defendant's scheme has in the past involved and continues to involve a calculated and deceitful sales campaign, and equally egregious failure and refusal to take required, timely, and adequate corrective actions to prevent catastrophic injury to its customers, such as Mr. Bryant.

6. Defendant spends billions of dollars each year trying to persuade doctors to prescribe their particular drugs. There are, however, strict FDA regulations about the form and content of such promotion. In fact, it is unlawful for a manufacturer to promote any drug for a use not described in the approved labeling of the drug. 21 U.S.C. §§ 331(d), 352(f), and 355.

7. The purpose of this federal requirement is to protect patients by ensuring drug manufacturers will subject prospective uses of their drugs to randomized and well-controlled clinical trials to determine whether the drug is safe and effective for such uses. These requirements and meant to ensure that drug companies like Defendant give physicians and medical personnel trustworthy information, so that medications are prescribed appropriately.

8. Defendant's duty to test a use arises, under both common law and federal law, when the manufacturer learns of any adverse events concerning its sale of Amiodarone.

9. As described in further detail herein, in 1998, Upsher received FDA approval to market and sell Amiodarone only as a drug of last resort for patients suffering from documented recurrent life-threatening ventricular fibrillation and ventricular tachycardia; and further, only when these conditions would not respond to other available antiarrhythmic drugs and therapies.

10. Shortly after approval, however, Upsher, and its hired agents embarked on a course of conduct the purpose of which was to increase Amiodarone sales as an initial, first-line

antiarrhythmic medication, for which Amiodarone has never received FDA approval, i.e. off-label use.

11. Defendant knew of the extreme dangers and catastrophic injuries and death caused by Amiodarone -- known through adverse events reporting customer and physician communications, and other sources -- which existed for almost 13 years when they affirmatively entered the market for Amiodarone.

12. Defendant recognized a significant profit potential in the off-label promotion and sale of Amiodarone as a first-choice cardiac drug for non-life threatening heart ailments.

13. Defendant tracked and had full knowledge of the number of prescriptions written for Amiodarone to be given as a first-line cardiac drug, and has, through various means designed to conceal its involvement, promoted and conspired together and with others to promote the use of Amiodarone as an initial, first-line therapy for arrhythmia and other heart ailments. Defendant decided to avoid the normal regulatory process of the FDA pertaining to the marketing of a new use of a drug. The decision was also made to actively conceal the means that would be used to market the drug.

14. Defendant's scheme was implemented so Defendant could tap into the enormous market for Amiodarone in the United States. Ultimately, Defendant's actions proved successful. For example, profits from Amiodarone sales earned Upsher millions of dollars, due mostly to off-label uses.

15. Upon information and belief, and at all material times hereto, Defendant was aware from multiple sources, and that the majority of Defendant's Amiodarone prescriptions was, and is currently, written for off-label purposes, and the majority of Defendant's product was used for off-label uses.

16. Defendant's scheme, described in more detail below, ultimately deceived Plaintiff, physicians, pharmacists, and consumers into believing that prescribing and taking Amiodarone for the off-label uses that Defendant promoted was appropriate even though Defendant knew FDA approval had not been granted and, moreover, there was significant medical-scientific evidence suggesting Amiodarone was very dangerous.

## II. PARTIES

17. Plaintiff, Harvey Bryant, is an adult individual and resident of the state of Oklahoma.

18. Defendant Upsher-Smith Laboratories is a Minnesota corporation with its principal place of business in Minneapolis, Minnesota, and includes all of their predecessor entities and their entire past and present component, subsidiary, and affiliate entities.

19. At all material times, every reference made in this Complaint to any corporate Defendant includes its predecessors, successors, parents, subsidiary, affiliates, and divisions of the corporation for the corresponding time period.

20. Whenever reference is made to any act, deed, or transaction of Defendant, the allegation means that the corporation engaged in the act, deed, or transaction by or through its officers, directors, agents, employees, or representatives while they were actively engaged in the corporation's management, direction, control, or business affairs.

## III. JURISDICTION & VENUE

21. Jurisdiction is proper in this District. Specifically, Defendant:

a. Is qualified to do business in this State;

b. Carries on a continuous and systematic part of its general business in this State;

c. Transacts business in this State;

d. Caused harm or tortious injury to the Plaintiff by an act or omission in this State;

e. Caused harm or tortious injury to the Plaintiff in this State by an act or omission outside this State.

22. The amount in controversy exceeds Seventy-Five Thousand Dollars ($75,000.00).

23. Venue is proper because this is an action against corporations that regularly conduct business in Johnston County, where the Plaintiff resides, as well as throughout the State of Oklahoma.

## IV. ADDITIONAL FACTUAL ALLEGATIONS

24. At all material times, Upsher manufactured, created, designed, developed, tested, licensed, labeled, packaged, distributed, supplied, marketed, advertised, promoted, sold, and/or otherwise distributed in interstate commerce, the drug Amiodarone and also manufactured Amiodarone for other companies. Moreover, each Defendant herein prepared and filed documents and materials with the United States Food and Drug Administration (FDA) and United States Patent and Trademark Office (USPTO) in connection with the approval process for the drug Amiodarone.

25. Amiodarone is a drug of last resort for consumption by patients suffering from documented recurrent life-threatening ventricular fibrillation and ventricular tachycardia. Further, the drug is for use only when these particular conditions do not respond to other available antiarrhythmic drugs and therapies.

26. Amiodarone is fat-soluble, and tends to concentrate in tissues including fat, muscle, liver, lungs, and skin. This confers a high volume of distribution and long half-life -- the amount of time it takes for one-half of an administered drug to be lost through biological

processes (metabolism and elimination). Because of this long half-life, Amiodarone's dangerous properties continue to cause injuries in patients long after they have ceased using the drug, including vision loss and blindness.

27. FDA regulations require any pharmaceutical company to seek and obtain FDA approval before any new drug may be marketed. Once approval is granted, a drug may only be promoted for the approved use at the approved damage.

28. Upsher must submit an application to the FDA seeking approval of the drug for off-label use; the manufacturer must provide its marketing materials to the FDA prior to dissemination; the materials must be in unabridged form; and the manufacturer must include disclosures that the materials pertain to an unapproved use of the drug, and, if the FDA deems it appropriate, "additional objective and scientifically sound information . . . necessary to provide objectivity and balance." 21 U.S.C. § 360aaa, *et seq*. Upsher's dissemination of information in violation of these provisions violated the Food, Drug and Cosmetic Act ("Act"), 21 U.S.C. § 331(z).

29. All prescription drugs require approval by the Food and Drug Administration (FDA) before they may be marketed. Manufacturers of new drugs submit a new drug application (NDA) to the FDA. 21 U.S.C. § 355(a)-(b). An NDA must include information about the drug's safety and efficiency gleaned from clinical trials. *Id.* at §§ 355(b), (d). It must also propose a label reflecting appropriate use, warnings, precautions, and adverse reactions. 21 C.F.R. § 201.56.

30. Of paramount importance is that drug labels are subject to change. New risks may become apparent only after the drug has been used more widely and for longer periods. When Upsher has received "reasonable evidence of an association of a serious hazard with a

drug[,]" the drug's label must be revised; "a causal relationship need not have been proved." 21 C.F.R. § 201.57(e) (redesignated as 21 C.F.R. § 201.80(e) in 2006, after the conduct at issue here). Upsher cannot distribute a "misbranded" drug, 21 U.S.C. §§ 331(a)-(b), including a drug whose "labeling is false or misleading in any particular." *Id.* at § 352(a). The FDA has several enforcement mechanisms to ensure that drugs with misleading labels are taken off the market. See, e.g., *Id.* at § 333, 355(e).

31. There are several procedures in 21 C.F.R. § 314.70 by which a manufacturer, such as Upsher, is required to supplement its application and propose changes to the drug or its label. "Major changes" require the FDA's prior approval through a prior approval supplement. 21 C.F.R. § 314.70(b). Manufacturers may implement "moderate changes," including changing a label to strengthen a warning based on newly acquired information, through a Changes Being Effected (CBE) supplement. 21 C.F.R. § 314.70(c)(6)(iii)(A)-(D). Manufacturers may implement CBE changes before the FDA formally approves them.

32. After *Wyeth v. Levine*, Upsher's argument that Congress silently intended to grant the manufacturers of most prescription drugs blanket immunity from state tort liability when they market inadequately labeled products, fails. Such a premise, as has been advanced by Upsher is baseless and void as against public policy.

33. In *Wyeth*, the Supreme Court concluded that multiple reports of an adverse experience with a drug provided the scientific substantiation to justify a manufacturer's, such as Upsher, request to change a label.

34. Upsher is required by the FDA to collect and report adverse drug experiences. 21 C.F.R. § 314.98, referencing 21 C.F.R. § 314.80. If Defendant had performed its obligations, and also taken note of the accumulation of adverse experience reports and the published medical

studies about Amiodarone and the Amiodarone drugs it manufactured and marketed, they would have had substantial substantiation to warrant label changes, which, in turn, would have provided warning to the Plaintiff.

35. The regulatory framework makes clear that Upsher *must take steps to warn its customers when it learns it may be marketing an unsafe drug*. Upsher was, at all times material hereto, subject to the requirement that their labeling "shall be revised as soon as there is reasonable evidence of an association of a serious hazard with a drug[.]" 21 C.F.R. § 201.57(e).

36. As discussed herein, Upsher did nothing significant to strengthen the label despite reasonable evidence of the drug's association with a serious hazard. Upsher cannot passively accept the inadequacy of their drug's label as they market and profit from it. See, e.g. *Wyeth*, 129 S.Ct. at 1202 ("The FDA has limited resources to monitor the 11,000 drugs on the market[.] . . . [M]anufacturers, not the FDA, bear primary responsibility for their drug labeling[.]"). The statute itself empowers the FDA to withdraw approval for a drug that is "misbranded" due to an insufficient label. 21 U.S.C. §§ 331(a)-(b), 352(a).

37. Upsher was required, at all times material hereto, to alert the agency to any new safety hazard associated with its product.

38. Upsher was required to maintain record keeping and reporting of adverse drug experiences post marketing.

39. In addition to proposing a label change, Upsher should have suggested that the FDA send out a warning letter to health care professionals concerning atrial fibrillation and associated permanent blindness from the ingestion of its Amiodarone. When the FDA first adopted its labeling regulations, well before the Hatch-Waxman Amendments, it stated that the requirements "do not prohibit a manufacturer . . . from warning health care professionals

whenever possibly harmful adverse effects associated with the use of the drug are discovered." 44 Fed. Reg. 37434, 37447 (June 26, 1979); see also CDER, Manual of Policies and Procedures (MAPP) 6020.10, NDAs: "Dear Health Care Professional" Letters (July 2, 2003) (guidance document).

40. Upsher can and must warn their customers of the risk of blindness and other catastrophic injury through such letters. The letters are considered regulated labeling, 21 C.F.R. §§ 202.1(1)(1), (2), and under the FDAAA, the FDA sends the letters out on behalf of ANDA holders if it determines that such a letter is a necessary part of a risk evaluation and mitigation strategy. 21 U.S.C. § 355-1(i)(2).

41. To state the obvious, Upsher marketed Amiodarone for uses not approved by the FDA. Upsher was not compelled to sell or distribute Amiodarone. When they realized their label was insufficient, they could have simply stopped selling the product. Instead, they placed Amiodarone on the market with inadequate labeling and continued to generate substantial profits from its sales, while causing catastrophic injury to customers such as the Plaintiff.

42. Because Plaintiff's injuries resulted from Defendant's failure to take steps to properly test and study the drug in light of the more than 15 years of surveillance leading to the Defendant's manufacture, sale, and distribution of the drug, and the several years of post-marketing surveillance available to them leading to Plaintiff's consumption of the drug, then they should be held liable.

43. Similarly, because Plaintiff's injuries resulted from these defendants' failure to properly or adequately warn about Amiodarone after more than 15 years of surveillance leading to these defendants' manufacture, sale, and distribution of the drug, and the several years of post-

marketing surveillance available to Upsher, leading to Plaintiff's consumption of the drug, then Upsher should be held liable.

44. Upsher is required to collect and report adverse drug experiences with their products. 21 C.F.R. § 314.98, referencing 21 C.F.R. § 314. 80. Upsher failed to adequately do so.

45. As set forth herein, Plaintiff alleges that Upsher had merely taken note of the accumulation of adverse drug experiences reports and the published medical studies about Amiodarone, they would have had more than sufficient substantiation to warrant a label change.

46. Congress and the FDA have viewed state tort law as complementing, not obstructing, the goals of the FDCA. *Wyeth*, 129 S.Ct. at 1199-1200 (Congress "determined that widely available state rights of action provided appropriate relief for injured [drug] consumers" and that "state-law remedies further consumer protection by motivating manufacturers . . . to give adequate warnings."); *Id.*. at 1197 ("[T]he statute contemplates that federal juries will resolve most misbranding claims[.]"). "If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005).

47. On or about April 30, 1998, Defendant Upsher introduced Pacerone into the United States' stream of commerce as a branded generic form of Amiodarone. On this date, Defendant Upsher received approval for Pacerone, pursuant to its Abbreviated New Drug Application (ANDA) used for generic-drug approval, from the FDA (ANDA No. 075135).

48. Because Pacerone was an ANDA-approved drug and a generic form of Cordarone, its manufacturer, Defendant Upsher was imputed with all knowledge regarding Cordarone, including any and all pre- and post-market testing, studies, surveys, labeling,

warnings, surveillance, adverse medical events, restrictions, approved uses, off-label/unapproved uses, risks, and dangers.

49. Further, as an ANDA-approved drug manufacturer for Amiodarone, this Defendant had an affirmative obligation to initiate and take and appropriate actions to prevent injury and death associated with the drug. Upsher had knowledge of and tracked the prescriptions written for the unapproved off-label uses of Amiodarone.

50. Identical to Cordarone, Pacerone was approved only as a drug of last resort for patients suffering from documented recurrent life-threatening ventricular fibrillation and ventricular tachycardia; and further, only when these conditions would not respond to other available antiarrhythmic drugs and therapies. Upsher never sought any further approval for treatment of atrial fibrillation.

51. On or about May 28, 1998, the FDA sent violation communications to Defendant Upsher regarding the FDA's determination that Upsher had violated the Act and its regulation(s) by, *inter alia*, disseminating false and misleading materials to physicians and the public without adequate risk information concerning the use of Amiodarone. Upsher misrepresented Amiodarone's indications and usage, efficacy, risks, and benefits. Further, Upsher intentionally failed to submit marketing materials to the FDA in violation of the Act.

52. On or about April 1, 1999, the FDA required Defendant Upsher to initiate a study on the effect of food consumption on Amiodarone ingestion, as insufficient evidence existed regarding the drugs interactions with food.

53. On or about May 17, 1999, the FDA required Defendant Upsher to change its labeling, warnings, and packaging in accordance with changes made by Defendant Wyeth (detailed above).

54. At all material times including through the present date, Defendant Upsher willfully failed and refused to actively and affirmatively monitor Amiodarone's off-label, unapproved uses insofar that such uses caused catastrophic injuries and death. Defendant Upsher, however, continued to promote Amiodarone for unapproved uses.

55. Upsher manufactured Amiodarone under marketing brand name Pacerone from 1998 through the present date.

56. Upsher also marketed Amiodarone for a generic company, Taro Pharmaceutical.

57. Upsher also manufactured Amiodarone under the name Geneva.

58. Upsher also manufactured Amiodarone for a generic company, Sandoz, which was distributed without disclosure of the manufacturer's name.

59. Upsher engaged in other joint ventures and marketing and manufacturing ventures, which Upsher has failed to disclose to the Plaintiff.

60. Before entering the market to manufacture, sell, and distribute Amiodarone, Upsher had actual or constructive knowledge of the dangerous history of Amiodarone's high risks for catastrophic injury, including blindness, through the FDA's oversight of innovator Wyeth, including the FDA's specific enforcement actions regarding the marketing and labeling of the drug Amiodarone.

61. Upon information and belief, Upsher was aware that in May of 1995, the Australian Government's Therapeutic Goods Administration (that country's counterpart to the U.S. FDA), issued an Australian Adverse Drug Reactions Bulletin, emphasizing that Amiodarone was appropriate only for use in the treatment of ventricular and supraventricular arrhythmias. Notably, this Bulletin highlighted that "the drug [Amiodarone] is known to have multiple adverse effects, which can involve most organ systems," and again stressed that

"Amiodarone is only to be used in patients with serious arrhythmias where there is no safer drug therapy."

62. Upon information and belief, Upsher was aware that on or about April 29, 1996, the FDA required Wyeth to change its labeling, warnings, and packaging for Amiodarone; specifically, adding new warnings or revising minimalist warnings regarding the following:

a. Carcinogenesis;

b. Mutagenesis;

c. Impairment of fertility, pregnancy;

d. Neonatal hypo- or hyperthyroidism.

63. Upon information and belief, Upsher knew that the severity of catastrophic adverse reactions, including death, led Wyeth to discontinue production and distribution of Cordarone in Canada on or about September 10, 1996. Upsher would have known about this development through its surveillance of Amiodarone sales leading to its decision to enter the market for same.

64. Upon information and belief, Upsher was aware that on or about February 11, 1997, the FDA issued a warning letter Wyeth regarding Amiodarone's understated or incorrect labeling and warnings based on the FDA's medical research.

65. Upon information and belief, Upsher was aware that on in 1998 -- the year in which it was preparing to bring its generic version of Amiodarone to market -- the FDA issued a Written Request for Pediatric Studies under Section 505A of the Act to Wyeth regarding Amiodarone. Upon information and belief, the basis for this request was that insufficient tests, surveys, and studies had been conducted regarding Amiodarone consumption by pediatric patients, although there was knowledge by Defendant and other drug manufacturers and in the

medical community that off-label use of Amiodarone in pediatric patients was being more and more common.

66. Upon information and belief, Upsher was aware that on in 1998 -- the year in which it was preparing to bring its branded generic version of Amiodarone to market -- the FDA issued a letter to Wyeth requiring that company to change its labeling, warnings, and packaging for Amiodarone; specifically, adding new warnings or revising minimalist warnings regarding the following:

a. Mortality (based upon the European Infarct Amiodarone Trial and Canadian Myocardial Infarct Trial);

b. Precautions regarding volatile anesthetic agents for Amiodarone users undergoing surgery;

c. Carcinogenesis;

d. Mutagenesis;

e. Impairment of fertility, pregnancy;

f. Neonatal hypo- or hyperthyroidism.

67. Upon information and belief, Upsher monitored Wyeth's sales and promotional practices for Amiodarone, including in 1998 -- the year in which it was preparing to bring its branded generic version of Amiodarone to market -- and had knowledge that on or about December 6-10, 1998, Wyeth sponsored a CME for the 33rd Midyear Clinical Meeting of the American Society of Health-System Pharmacists. This CME was for healthcare providers, including pharmacists, as part of Defendant's ongoing promotion of Amiodarone for off-label purposes. As part of the CME, Wyeth produced and distributed to attendees, a 68-page official looking, peer review-appearing magazine, "The Pharmacist Reporter (July 1999, Vol. 4, No. 5)." This publication was actually a promotional bulletin highlighting Wyeth's goal for Amiodarone:

increased off-label use. Among the topics addressed in various articles in "The Pharmacist Reporter," several of which appear to soften, downplay, and/or minimize Amiodarone's devastating side effects, were the following:

a. "An Aggressive Treatment Strategy for Atrial Fibrillation";

b. "Use of Amiodarone in Patients Undergoing Cardiothoracic Surgery";

c. "A Possible New Standard of Care for Prehospital Cardiac Arrest."

68. After Upsher started its manufacture, sale, and distribution of its branded generic Amiodarone, it knew or should have known that on or about October 8, 1999, the FDA issued a letter to Wyeth requiring Defendant to change its labeling, warnings, and packaging for Amiodarone; specifically, adding new warnings or revising minimalist warnings regarding the following:

a. Clinical pharmacology and pharmokinetics, in that food consumption increases Amiodarone's absorption rate;

b. Geriatric use, whereby clinical studies of Amiodarone in persons 65 and older had not been conducted;

c. Dosage and administration, in that food consumption must be addressed in dosing and loading doses are to be used.

69. After Upsher started its manufacture, sale, and distribution of its generic Amiodarone, it knew or should have known that on or about January 12, 1999, the FDA issued a letter to Wyeth requiring Defendant to change its labeling, warnings, and packaging for Amiodarone; specifically, adding new warnings or revising minimalist warnings regarding Geriatric use, whereby clinical studies of Amiodarone in persons 65 and older had not been conducted.

70. After Upsher started its manufacture, sale, and distribution of its branded generic Amiodarone, it knew or should have known that on or about February 12, 1999, the FDA issued

a letter to Wyeth requiring Defendant to change its labeling, warnings, and packaging for Amiodarone; specifically, adding new warnings or revising minimalist warnings regarding the effects of food consumption on dosage and administration.

71. Upsher knew and was affected by the February of 2002, the Australian Government's Therapeutic Goods Administration issuance of an Australian Adverse Drug Reactions Bulletin, alerting healthcare professionals in that country that numerous adverse medical events associated with Amiodarone had been reported to the TGA in 2002 and 2001, including Amiodarone-induced pulmonary toxicity and deaths. The TGA warning contained the following important information for healthcare professionals:

> "Although commonly insidious in onset, amiodarone-induced pulmonary toxicity may develop rapidly. The lowest effective dose should be used, and patients should be instructed to report any dyspnoea or non-productive cough.[1] Amiodarone also has other toxicities including hepatotoxicity which can cause cirrhosis and hepatic failure, cardiovascular effects including bradycardia and tachycardia, skin reactions including photosensitivity and discolouration, neurotoxicity including ataxia and peripheral neuropathy, as well as both corneal deposits and hyper- and hypothyroidism."

72. Upsher knew or should have known that on or about December 18, 2002, the FDA issued a letter to Wyeth requiring Defendant to change its labeling, warnings, and packaging for Amiodarone; specifically, adding new warnings or revising minimalist warnings regarding adverse drug interactions with immunosuppressant static drugs, resulting in rhabdomyolysis.

73. Once in the market of manufacturing, selling, and distributing its branded generic Amiodarone, Upsher knew that on or about December 19, 2002, the FDA issued a warning letter

to Wyeth requiring Defendant to correct understated warnings and/or issue new warnings regarding the following:

a. Acute onset (days to weeks) of pulmonary toxicity;

b. Patients having preexisting pulmonary disease have poorer prognosis if pulmonary toxicity develops;

c. Post-marketing reports include possible fatal respiratory disorders (including distress, failure, arrest, ARDS), fever, dyspnea, cough, hemoptysis, wheezing, hypoxia, and pulmonary infiltrates).

74. Once in the market of manufacturing, selling, and distributing its branded generic Amiodarone, Upsher knew that in 2003, the FDA issued a warning letter to Wyeth, requiring Defendant change its labeling, warnings, and packaging for Amiodarone; specifically, adding new warnings or revising minimalist warnings regarding the following:

a. worsened arrhythmia;

b. thyroid abnormalities;

c. drug interactions (protease inhibitors, histamine antagonists, immunosuppressives, antibiotics, cardiovasculars, antiarrhythmics, antihypertensives, anticoagulants);

d. other substance (grapefruit juice, herbal supplements) interactions;

e. electrolyte disturbances; and

f. nursing mothers passing the drug to newborns through breast milk.

75. Optic neuropathy is an underreported adverse side effect of Amiodarone that was not adequately disclosed by Upsher to the Plaintiff or his health care providers.

76. It became well known to Upsher, prior to their manufacture, sale, and distribution of Amiodarone, that Amiodarone use had resulted in vision loss and permanent blindness.

77. In fact, once in the market of manufacturing, selling, and distributing its branded generic Amiodarone, Upsher knew that non-party Wyeth had previously been forced by the

Canadian Government to change the drug's labeling in Canada in this regard, and upon information and belief, these defendants had actual knowledge of this specific adverse reaction.

78. Upsher's pharmaceutical sales and marketing directors encouraged their respective sales representatives to visit physicians' offices throughout the United States to promote and over promote the drug for off-label use, such as atrial fibrillation.

79. Upsher was aware of, and wanted a piece of, Wyeth's more than Three Billion ($3,000,000,000) in sales for Amiodarone.

80. Upsher was on notice, by no later than 1998, when they began manufacturing Amiodarone, that severe damage and inflammation of the nerve serving the eyes (optic neuropathy/optic neuritis) were side effects of the ingestion of Amiodarone which can cause permanent blindness.

**1. Upsher, Knowing the Complicated and Troubled History of Cordarone and Amiodarone, Nevertheless Entered This Market With Their Own Branded Generic Versions of Amiodarone known as Pacerone**

81. Further, as an ANDA-approved drug manufacturer for Amiodarone, Upsher had an affirmative obligation to initiate and take and appropriate actions to prevent injury and death associated with the drug.

82. Like all previously FDA-approved Amiodarone, Upsher knew that Amiodarone and Pacerone were approved only as a drug of last resort for patients suffering from documented recurrent life-threatening ventricular fibrillation and ventricular tachycardia; and further, only when these conditions would not respond to other available antiarrhythmic drugs and therapies.

83. Upon information and belief, the FDA sent violation communications to Defendant regarding the FDA's determination that Defendant had violated the Act and its

implementing regulation by, *inter alia*, disseminating false and misleading materials to physicians and the public without adequate risk information concerning the use of Amiodarone. Defendant misrepresented Amiodarone's indications and usage, efficacy, risks, and benefits. Further, Defendant intentionally failed to submit marketing materials to the FDA in violation of the Act.

84. At all material times, Defendant willfully failed and refused to actively and affirmatively monitor Amiodarone's off-label, unapproved uses insofar that such uses caused catastrophic injuries and death. Defendant, however, continued to promote Amiodarone for unapproved uses.

85. Like all previously FDA-approved Amiodarone, Defendant's Amiodarone was approved only as a drug of last resort for patients suffering from documented recurrent life-threatening ventricular fibrillation and ventricular tachycardia; and further, only when these conditions would not respond to other available antiarrhythmic drugs and therapies.

86. Upon information and belief, the FDA sent violation communications to Upsher the FDA's determination that it had violated the Act and its implementing regulation by, *inter alia*, disseminating false and misleading materials to physicians and the public without adequate risk information concerning the use of Amiodarone. Defendant misrepresented Amiodarone's indications and usage, efficacy, risks, and benefits. Further, Defendant intentionally failed to submit marketing materials to the FDA in violation of the Act.

87. At all material times, Upsher willfully failed and refused to actively and affirmatively monitor Amiodarone's off-label, unapproved uses insofar that such uses caused catastrophic injuries and death. Upsher, however, continued to promote Amiodarone and Pacerone for unapproved uses.

88. At all material times, Upsher, respectively, jointly and severally, have had actual or constructive knowledge that Amiodarone and Pacerone cause and contribute to severe and disabling medical conditions and death, including, without limitation, the following: pulmonary toxicity, pulmonary fibrosis, hepatic damage and failure, neurotoxicity, neonatal hypothyroidism, birth defects, optic neuritis, toxic optic neuropathy, blindness, peripheral neuropathy, heart damage and failure, hypotension, serious exacerbation of arrhythmias, and congestive heart failure.

89. Upon information and belief, Upsher has received information concerning more than One Thousand (1,000) deaths resulting from the use of Amiodarone.

90. Upon information and belief, Upsher has received information concerning more than one hundred (100) cases of vision impairment, including blindness, as well as thousands of cases of severe medical conditions resulting from the use of Amiodarone and Pacerone, including, without limitation, pulmonary toxicity, pulmonary fibrosis, lung damage, hepatic damage and failure, neurotoxicity, peripheral neuropathy, neonatal hypothyroidism, optic neuritis, toxic optic neuropathy, blindness, serious exacerbation of arrhythmias, and congestive heart failure.

91. Some of these events, upon information and belief, were reported directly to the company by healthcare providers, as well as patient-consumers.

92. Additionally, in addition to these direct notices of adverse events, the Food and Drug Administration (FDA) had, and continues to have, in effect, an adverse reaction surveillance system for all regulated drugs, including Amiodarone, called the Adverse Event Reporting System (AERS).

93. Upon information and belief, the AERS has placed Defendant on notice of numerous instances of blindness and other catastrophic injuries caused by ingestion of Amiodarone.

94. At all material times, Defendant failed to disclose to the FDA, health care professionals, consumers, or Plaintiff, of the information they possessed concerning the incidents , optic neuritis, toxic optic neuropathy, blindness, actual adverse medical events, injuries, and deaths suffered by Amiodarone users. Instead, upon information and belief, Upsher actively promoted Amiodarone and Pacerone for off-label, unapproved uses as described herein through various means, including, but not limited to, the following:

a. Direct-to-physician and direct-to-pharmacist promotion through sales representatives;

b. Promotion through funding and manipulation of so-called "educators" who organize and arrange continuing medical education (CME) courses for physicians and pharmacists;

c. Formulation of unlawful conspiracies with certain medical marketing and medical "education" entities to promote –without appearing to promote – off-label uses;

d. Sponsorship and funding of the production of CME materials;

e. Cultivation and development of so-called "opinion leaders" in local medical communities and support for the careers and research of those physicians, pharmacists, and researchers who advocate off-label uses;

f. Sponsorship of journal supplements and symposia on off-label uses for Amiodarone;

g. Placing (through sponsorship of limited trials, studies, and surveys) of medical literature databases showing positive effects (already established) on risk factors with the twin purposes of overwhelming any independent study showing negative effects on different risk factors, and causing earnest but time-crunched physicians to be impressed with the sheer quantity of favorable (but redundant) studies on a MedLine, or medical library, search;

h. Media advertisements and brochures, some of which were disguised as "educational materials";

i. Various other forms of marketing and promotion.

95. Upon information and belief, in accepting the benefits of other drug companies efforts in promoting off-label uses of Amiodarone by sponsoring CME conferences and materials, journal supplements, redundant trials, and the work and careers of favorably disposed opinion leaders, Defendant would sometimes escape disclosure for any role at all in the presentation of its desired view.

96. Additionally, upon information and belief, Defendant's and/or its agents' pharmaceutical sales representatives actively promoted their Amiodarone to prescribing physicians for the off-label uses openly promoted by competing drug companies.

97. At all material times, despite FDA warnings and thousands of adverse patient experiences, Upsher continued their fraudulent marketing, promotional, and sales practices from 1998 through the present date.

98. At all material times, Upsher concealed information about catastrophic injuries, permanent blindness and death, and thousands of serious adverse medical events from the FDA, health care professionals, and consumers, including Plaintiff.

99. At all material times, the Amiodarone manufactured and/or supplied by Upsher was and is unaccompanied by proper warnings regarding all possible adverse side effects and comparative severity and duration of such adverse effects; the warnings given did not and do not accurately reflect the severity or duration of the adverse side effects or the true potential and/or likelihood or rate of the side effects. This is particularly so with regard to off-label use.

100. At all material times, Upsher failed to warn of material facts regarding the safety and efficacy of Amiodarone, such that this drug would likely have never been approved, and no physician would have been able to prescribe this drug for use in the United States.

101. At all material times, Upsher failed to perform adequate testing in that adequate testing would have shown that Amiodarone possessed serious potential side effects with respect to which full and proper warnings accurately and fully reflecting symptoms, scope, and severity should have been made with respect to the use of Amiodarone, particularly for off-label use.

102. For example, although Defendant knows, should have known, and currently knows that the majority of patients consuming Amiodarone are senior citizens, including those aged 55 and over, Upsher has failed and refused to conduct testing, studies, surveys, and/or report the results of same regarding Amiodarone use in this age group.

103. At all material times, the Amiodarone manufactured, distributed, and/or supplied by Defendant was defective due to inadequate post-marketing warning and instruction because, after Defendants knew or should have known of the risk of injury from Amiodarone, especially in off-label use, Defendants failed to provide adequate warnings to physicians, users or consumers of Amiodarone, including the Plaintiff, and continued to aggressively sell Amiodarone, including for off-label use.

104. At all material times, while Upsher concealed this adverse event information, they simultaneously engaged in a massive and fraudulent marketing and promotional scheme in which they aggressively and fraudulently promoted Amiodarone for uses never authorized by the FDA. In fact, Defendant marketed, promoted, and "pushed" Amiodarone, not as a drug of last resort, but as a drug suitable as an initial therapy and to treat non-life-threatening heart conditions.

105. At all material times, Defendant, respectively, jointly and severally, also promoted Amiodarone for heart conditions less severe than life-threatening ventricular arrhythmia (the only purpose for which the drug originally received FDA approval).

106. Upsher engaged in a conspiracy of silence regarding off-label use of Amiodarone, choosing to market and promote the drug for off-label use, and then feigning ignorance before the FDA, health care providers, and consumers. They failed and refused to conduct thorough testing on the side effects of Amiodarone, despite knowing that their scheme to promote the drug for off-label uses had been, and continues to be, successful.

107. Defendant has engaged in this calculated and coordinated silence despite their knowledge of the growing public acceptance of misinformation and misrepresentations regarding both the safety and efficacy of the use of Amiodarone, and did so because the prospect of significant future profits outweighed their concern regarding health and safety issues, all to the significant detriment of the public and Plaintiff.

108. At all material times, Upsher's affirmative misrepresentations and omissions have so infected the market in the United States that physicians and consumers relied on Upsher's fraud, respectively, to the detriment of their patients and themselves.

109. Under increased FDA scrutiny and mandates, Upsher has been forced to correct and change their warning labels, and add new warnings, for Amiodarone for adverse side effects about which they knew long before being required to make such changes.

110. Nevertheless, at all material times, the warnings for Amiodarone in effect during the relevant time period were vague, incomplete, and/or otherwise wholly inadequate, both substantively and graphically, to alert prescribing physicians, pharmacists, and consumer patients of the actual risks associated with this drug.

111. At all material times, Upsher's deception, concealment, and fraudulent marketing and promotion has been so pervasive throughout this State and the United States, that prescribing physicians and consumer patients have during the relevant time period still believe that Amiodarone is an acceptable initial, secondary, or otherwise early-stage anti-arrhythmic intervention. These deceptive techniques served (and continue to serve) Upsher in several ways, including: (1) instilling Upsher's desired view about Pacerone's off-label uses among health care providers; (2) Upsher hoped that, by concealing its agency in these activities, they would escape the legal ramifications of its unlawful promotional activities; and (3) boost Upsher's profits for the drug.

112. At all material times, Upsher owed a duty to the health care providers, consumer patients, and Plaintiff herein, to engage in honest and non-deceptive practices; exercise due care under the circumstances, to exercise due care in the design, manufacture, marketing, promotion, sale, and distribution of Amiodarone; to provide a reasonably safe and non-defective drug; to provide adequate and appropriate warnings for said drug; to comply with federal guidelines, rules, and regulations; and/or to sell and distribute the drug in accordance with FDA restrictions.

113. At all material times, Upsher's represented Amiodarone as having approval, characteristics, uses, and benefits that the drug did not have.

114. At all material times, Upsher did design, create, test, develop, label, sterilize, package, manufacture, market, promote, advertise, distribute, sell, warn, and/or otherwise caused the product Amiodarone to be placed into the stream of commerce, and ultimately to be ingested by Plaintiff.

115. At all material times, Upsher willfully failed and refused to actively and affirmatively monitor Amiodarone's off-label, unapproved uses insofar that such uses caused

catastrophic injuries and death. Upsher, however, continued to sell Amiodarone for unapproved uses.

116. At all material times, Defendants, respectively, jointly and severally, engaged in a continuing course of fraud, concealment, material nondisclosure and omission, upon Plaintiff, which prevented Plaintiff from knowing or having reason to know of Upsher's misconduct as aforesaid.

## V. EQUITABLE/LEGAL TOLLING OF LIMITATIONS PERIOD(S)

117. Plaintiff incorporates the allegations contained in the preceding paragraphs.

118. Upsher omitted, suppressed, and/or concealed material facts concerning the health dangers and risks associated with approved and off-label use of Pacerone and Amiodarone, including, but not limited to, the risks of lung damage, liver damage, eye damage, birth defects, neurological damage, heart damage, and death.

119. Upsher engaged in calculated silence despite their knowledge of the growing acceptance by physicians and consumer patients, including Plaintiff, of the misinformation and misrepresentations regarding both the safety and efficacy of Amiodarone. Upsher committed this wrongful conduct because of the prospect of significant future profits caused them to ignore concerns regarding health and safety issues, all to the significant detriment of the public, including Plaintiff.

120. Upsher's actions as set forth herein constitute knowing omission, suppression, and/or concealment of material facts, made with the intent that others will rely upon such concealment, suppression, and/or omission, in connection with the marketing and promotion of Amiodarone.

121. Upsher's actions, as aforesaid, evidence lack of good faith, honesty in fact, and observance of fair dealing so as to constitute deceptive and unconscionable commercial practices.

122. Any applicable statutes of limitation and statutes of repose have been tolled by Upsher's affirmative acts of deliberate and fraudulent concealment.

123. Plaintiff could not have reasonably discovered Defendant's wrongful conduct as aforesaid.

124. Upsher is estopped from relying on any statute of limitations or repose defense because of their deceptive conduct.

125. Because of the self-concealing nature of Upsher's actions, and their affirmative acts of concealment, Plaintiff asserts the tolling of any applicable statutes of limitation and repose.

126. In 2004, certain Plaintiff class representatives brought a class action against Wyeth, Upsher and others on behalf of all persons who sustained personal injury from the ingestion of Amiodarone. *Westerlund et al. v. Wyeth et al.,* New Jersey, C.A. No.: MID-L-2174-05. On June 9, 2010, the Court entered an Order which provided in relevant part that Plaintiff Harvey Bryant could commence an individual action against Upsher on or before November 5, 2010. Defendant agrees that if timely filed by said date, they could not raise any statute of limitations defense to any of Plaintiff's claims. Accordingly, the Defendant has waived and is estopped from raising statute of limitations as a defense to any of Plaintiff's claims.

## VI. CAUSES OF ACTION

### COUNT I
### NEGLIGENCE

127. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

128. When Upsher placed its Amiodarone in the stream of commerce, Amiodarone was not accompanied by any meaningful warnings regarding the significant risk of medical conditions, including lung damage, liver damage, eye damage, neurological damage, birth defects, heart damage, other problems, and death, associated with the ingestion of Amiodarone. The warnings Defendants did provide did not accurately reflect the existence of the risk, let alone the incidence, symptoms, scope, and/or severity of such injuries.

129. Defendant failed to perform adequate testing concerning the safety of the drug Amiodarone in that adequate testing would have shown that Amiodarone poses a serious risk of medical conditions and injuries, including lung damage, liver damage, eye damage, neurological damage, birth defects, heart damage, other problems, and death, which would have permitted adequate and appropriate warnings to have been given by Defendant to prescribing physicians and the consuming public.

130. Defendant failed to effectively warn users and physicians that numerous other anti-arrhythmic agents, heart medications, and other modalities should be used and exhausted before prescribing Amiodarone.

131. Defendant had a duty to exercise reasonable care in the design, manufacture, sale, promotion, labeling, advertising, distribution, and otherwise release of Amiodarone products into the stream of commerce, including a duty to assure that the product did not cause users to suffer

from unreasonable, dangerous side effects when used alone or in foreseeable combination with other drugs.

132. Defendant, by and through their respective employees, agents, servants, and representatives, was careless, negligent, grossly negligent, reckless, and outrageous in the design, research, manufacture, testing, labeling, warnings provided, advertising, promotion, marketing, sale, distribution, and/or otherwise release of Amiodarone products into the stream of commerce, in approved and off-label form, in that they:

a. Failed to accompany the product with proper warnings regarding all possible adverse side effects associated with the use of Amiodarone;

b. Failed to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the drug Amiodarone;

c. Failed to provide adequate training and instruction to medical care providers for appropriate use of the drug Amiodarone;

d. Failed to advise the US medical profession, including physicians, pharmacists, and related health care providers:

i. that Amiodarone caused adverse effects identified herein;

ii. that patients using Amiodarone required close monitoring for signs or symptoms of adverse effects;

iii. that patients should be notified that if they experienced any signs or symptoms of adverse effects they should immediately discontinue use of the drug and contact their physician;

e. Failed to warn Plaintiff, prior to actively encouraging the sale of Amiodarone, either directly or indirectly, orally or in writing, about the following:

i. The need for a battery of diagnostic tests to be performed on the patient prior to ingesting Amiodarone to ensure against and/or discover potentially fatal side effects;

ii. The need for comprehensive, regular medical monitoring to ensure early discovery of potentially fatal side effects;

iii. The possibility of becoming disabled as a result of using the drug and/or having to undergo corrective testing, procedures, and surgery;

iv. That said side effects and injuries may become protracted, debilitating, difficult, and painful, necessitating lengthy surgeries and/or several visits to the doctor, clinic or hospital;

f. Failed to warn that the risks associated with the ingestion of Amiodarone would exceed the risks of other comparable forms of medication for heart irregularities;

g. Failed to effectively warn about the increased danger and potentially fatal relationship in combining the use of Amiodarone with various other drugs or use with certain identifiable disorders;

h. Marketed Amiodarone despite the fact that the risks of the drug were so high and the benefits of the drug were so speculative that no reasonable pharmaceutical company, exercising due care, would have done so;

i. Recklessly, falsely, and/or deceptively represented or knowingly omitted, suppressed, and/or concealed facts of such materiality regarding the safety and efficacy of Amiodarone from prescribing physicians and the consuming public, and that had prescribing physicians and the consuming public known of such facts, the drug Amiodarone would never have been prescribed to Plaintiff;

j. Remained silent despite its knowledge of the growing public acceptance of misinformation and misrepresentations regarding both the safety and efficacy of the ingestion of Amiodarone, and did so because the prospect of huge profits outweighed health and safety issues, all to the significant detriment of Plaintiff;

k. Failed to perform its post-manufacturing duty to warn which arose when it knew, or with reasonable certainty should have known, that its drug was being prescribed in a fatal or injurious combination or manner;

l. Failing to provide adequate, proper, and accurate warnings for this product;

m. Intentionally, recklessly, and negligently failing to ensure that prescribing physicians and ultimate users were adequately, properly, and accurately notified and/or warned of the dangers of said product;

n. Intentionally, recklessly, and negligently failing to investigate and analyze prior adverse reactions information in order to warn and/or notify physicians and ultimate users of the product's defects and dangers;

o. Negligence per se;

p. Intentionally and recklessly promoting and understating the risks and toxic effects of the product;

q. Intentionally and recklessly marketing, selling, and distributing the product for uses inconsistent with its FDA approval, including off-label use;

r. Failing to provide adequate information, training, and/or instruction to medical care providers for appropriate use of the product;

s. Failing to warn Plaintiff, prior to actively encouraging the sale of the product, either directly or indirectly, orally or in writing, about the following:

i. Amiodarone is to be used only as a last resort;

ii. Amiodarone is to be used only for recurrent life-threatening ventricular fibrillation and ventricular tachycardia;

iii. Amiodarone is only to be used when the conditions have not responded to other anti-arrhythmia drugs and therapies;

iv. Amiodarone had caused numerous deaths and serious injuries.

t. Being otherwise careless, negligent, grossly negligent, reckless, and acted with willful and wanton disregard for the rights of Plaintiff.

133. Despite the fact that the Upsher knew or should have known that Amiodarone caused unreasonable, dangerous side effects which many users would be unable to remedy by any means, Defendant continued to market Amiodarone to consumers, including Plaintiff, when there were safer alternative methods for treating arrhythmia and other cardiac irregularities.

134. Upsher knew or should have known that consumers such as Plaintiff would foreseeably suffer injuries as a result of the Defendant's failure to exercise ordinary care as described above.

135. Upsher's actions as described herein constitute knowing omissions, suppression or concealment of material facts, made with the intent that others rely upon such concealment, suppression, or omissions in connection with the marketing of Amiodarone.

136. Upsher's acts and omissions described herein demonstrate that Defendant acted unlawfully and negligently, used or employed unconscionable commercial and business practices, engaged in deception, fraud, false pretenses, false promises or misrepresentations, and/or perpetrated the knowing concealment, suppression, and/or omission of material facts with the intent that consumers, including Plaintiff, would rely upon such concealment, suppression, or omissions, in connection with the marketing, advertising, promotion, sale, and/or distribution of Amiodarone.

137. As the direct and proximate cause and legal result of the Upsher's failure to supply appropriate warnings for the drug Amiodarone, and as a direct and legal result of the negligence, gross negligence, and recklessness, other wrongdoing and actions of Upsher's described herein, Plaintiff Bryant ingested Pacerone, and has suffered severe injury, including permanent blindness.

138. Upsher's negligence was a proximate cause of the increased risk of harm suffered by the Plaintiff as previously set forth herein.

139. As a direct and proximate result of the Upsher's conduct as aforesaid, Plaintiff has suffered and continues to suffer serious and permanent physical and emotional injuries, has expended and will continue to expend large sums of money for medical care and treatment, has

suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured.

**WHEREFORE,** Plaintiff Bryant demands judgment against Defendant for compensatory and punitive damages, together with applicable interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

## COUNT II
## BREACH OF EXPRESS AND IMPLIED WARRANTIES

140. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

141. Defendant has breached the implied warranty of merchantability in that Defendant's Amiodarone was not reasonably fit for the approved and off label purposes for which its use was sold, intended, or reasonably foreseen. Moreover, the Amiodarone manufactured and sold by Defendant was defective on the date of its delivery to Plaintiff.

142. Defendant has also breached the implied warranty of fitness for a particular purpose. Amiodarone is not reasonably fit for the specific off label purposes for which Defendant knowingly sold it and for which the Plaintiff bought Amiodarone in reliance on Defendant.

143. By the conduct alleged, Defendant impliedly warranted to Plaintiff (and if applicable, Plaintiff's physicians) that the products were merchantable and fit for the purpose intended. These warranties were breached and Plaintiff was seriously injured and suffered permanent blindness.

144. As a direct and proximate result of one or more of these wrongful acts or omissions of Upsher, Plaintiff suffered profound injuries which are permanent and continuing in

nature; required and will require medical treatment and hospitalization; has become and will become liable for medical and hospital expenses; lost and will lose financial gains; has been and will be kept from ordinary activities and duties and will continue to experience mental and physical pain and suffering, all of which damages will continue in the future.

**WHEREFORE,** Plaintiff Bryant demands judgment against Defendant for compensatory and punitive damages, together with applicable interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

## COUNT III
## STRICT LIABILITY

145. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

146. Pacerone was (1) in a defective condition and unreasonably dangerous for its intended use; (2) the defect existed when the product left Defendant's control and (3) the defect was the proximate cause of the permanent blindness sustained by the Plaintiff.

147. Defendant's Pacerone was, at all times material hereto, defective in manufacture and unreasonably dangerous. Defendant could have prevented the Plaintiff's injury.

148. Defendant's Pacerone was also defective by reason of the Defendant's off-label marketing scheme, pursuant to which it marketed and promoted the drug for atrial fibrillation.

149. Defendant also failed to adequately warn health care providers of the serious risks of permanent blindness caused by Defendant's Pacerone.

150. Plaintiff sustained permanent blindness proximately caused by Defendant's Pacerone which has caused him to become legally blind in 2004 in both eyes.

151. As a direct and proximate result of the Defendant's conduct, Plaintiff's life has been irreparably destroyed. He is not able to care for himself any longer.

**WHEREFORE**, Plaintiff Bryant demands judgment against Defendant for compensatory damages, together with applicable interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

## COUNT IV
## FRAUD

152. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

153. At all material times, Defendant had actual knowledge and/or constructive knowledge, based upon reports, complaints, surveys, and clinical studies, that Amiodarone posed a serious risk of lung damage, liver damage, eye damage, birth defects, neurological damage, heart damage, and death, to consumers who used Amiodarone.

154. Defendant was under a duty to disclose this information to the Plaintiff under the common law as well as laws requiring Defendant not to engage in false and deceptive practices, and as otherwise alleged in this Complaint, because Defendant made representations and partial disclosures concerning the nature and quality of their product which they had a duty to correct, because Defendant was in a superior position to know the true state of the facts about the dangerous and defective nature of Amiodarone and its known risks to the Plaintiff.

155. At all material times, Defendant had a duty to disclose but intentionally omitted this information in its product labeling and/or intentionally failed to disclose fully and adequately the risk of personal injury resulting from Amiodarone to physicians and consumers, including Plaintiff, in order to market the drug and to avoid losses in sales of the drug. These deliberate

and intentional omissions of material facts and misrepresentations include, but are not limited to, the following:

a. Suppressing, failing to disclose, and mischaracterizing the known risks of ingesting Amiodarone;

b. Omitting material information showing that Amiodarone was medication of a "last resort";

c. Marketing, advertising, selling, distributing, and/or promoting Amiodarone for off-label uses;

d. Failure to timely and fully disclose the actual results of clinical tests and studies related to Amiodarone;

e. Failing to issue adequate warnings concerning the risks and dangers of ingesting Amiodarone which would disclose the nature and extent of side effects of Amiodarone;

f. Failing to disclose that adequate and/or standard and/or generally accepted pre-clinical and clinical testing had not been done;

g. Failing to disclose that adequate and/or standard and/or generally accepted standards for post-marketing testing had not been done;

h. Making the representations concerning the safety, efficacy, and benefits of Amiodarone as detailed in this Complaint without full and adequate disclosure of the underlying facts that rendered such statements and misleading.

156. Plaintiff did not know, and could not learn, the material facts and important information Defendant omitted and suppressed. The facts and information suppressed and concealed is material, and o such a nature that it can be reasonably presumed that the suppression and concealment of such facts caused, contributed to, and/or was a substantial factor in causing change to Plaintiff.

157. Even when Defendant was put on actual notice of high incidents of severe personal injuries and death, Defendant persisted in selling the product without taking action to protect consumers, including Plaintiff.

158. At all material times, Defendant intentional misrepresentations and material nondisclosures, as aforesaid, were done with the knowledge that they were false when made.

159. As a result of Defendant's fraud, suppression and omission of facts, Plaintiff to his detriment in purchasing and ingesting Amiodarone, which they would not have purchased or ingested had they been told the truth, and should be reimbursed what they spent.

160. As a result of Defendant's practices, Plaintiff has suffered actual damages in that they purchased and ingested Amiodarone which is dangerous and defective that has caused and will continue to cause Plaintiff members expenses for medical testing, health monitoring and/or treatment, which they incurred in the past, which continues to date, and will continue into the future.

161. As a direct and proximate result of one or more of those wrongful acts or omissions of the Defendant, Plaintiff suffered profound injuries; required medical treatment and hospitalization; and Plaintiff became liable for medical and hospital expenses.

**WHEREFORE,** Plaintiff Bryant demands judgment against Defendant for compensatory and punitive damages, together with applicable interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

## VII. DEMAND FOR JURY TRIAL

Plaintiff in the above-styled case hereby demands a trial by jury of all issues so triable as a matter of right.

Dated: November 3, 2010

Respectfully submitted,

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